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## PATENT COOPERATION TREATY

## PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

REC'D 17 JUN 2004

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| Applicant's or agent's file reference<br>028870-265   | FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416) |  |
| International application No.<br>PCT/US03/07087   | International filing date (day/month/year)<br>07 March 2003 (07.03.2003)   | Priority date (day/month/year)<br>07 March 2002 (07.03.2002) |
| International Patent Classification (IPC) or national classification and IPC<br>IPC(7): A61K 7/06 and US Cl.: 424/70.1, 70.12   |  |  |
| Applicant<br>USBIOMATERIALS CORPORATION   |  |  |
| <p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>5</u> sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of <u>0</u> sheets.</p> <p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the report</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input type="checkbox"/> Non-establishment of report with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p> |  |  |
| Date of submission of the demand<br>07 October 2003 (07.10.2003)  | Date of completion of this report<br>05 May 2004 (05.05.2004)  |  |
| Name and mailing address of the IPEA/US<br>Mail Stop PCT, Attn: IPEA/US<br>Commissioner for Patents<br>P.O. Box 1450<br>Alexandria, Virginia 22313-1450<br>Facsimile No. (703) 305-3230   | Authorized officer<br>Lakshmi Channavajjala<br>Telephone No. 703-308-1235  |  |

Form PCT/IPEA/409 (cover sheet)(July 1998)

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**I. Basis of the report****1. With regard to the elements of the international application:\***

- ☒ the international application as originally filed.
- ☒ the description:  
pages 1-19 \_\_\_\_\_ as originally filed  
pages NONE \_\_\_\_\_, filed with the demand  
pages NONE \_\_\_\_\_, filed with the letter of \_\_\_\_\_.
- ☒ the claims:  
pages 20-24 \_\_\_\_\_, as originally filed  
pages NONE \_\_\_\_\_, as amended (together with any statement) under Article 19  
pages NONE \_\_\_\_\_, filed with the demand  
pages NONE \_\_\_\_\_, filed with the letter of \_\_\_\_\_.
- ☒ the drawings:  
pages 1-19 \_\_\_\_\_, as originally filed  
pages NONE \_\_\_\_\_, filed with the demand  
pages NONE \_\_\_\_\_, filed with the letter of \_\_\_\_\_.
- ☐ the sequence listing part of the description:  
pages NONE \_\_\_\_\_, as originally filed  
pages NONE \_\_\_\_\_, filed with the demand  
pages NONE \_\_\_\_\_, filed with the letter of \_\_\_\_\_.

**2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.**  
These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

**3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:**

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

**4. ☐ The amendments have resulted in the cancellation of:**

- ☐ the description, pages NONE
- ☐ the claims, Nos. NONE
- ☐ the drawings, sheets/fig NONE

**5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\***

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International Application No.  
PCT/US03/

## V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

### 1. STATEMENT

Novelty (N)

Claims 1-34 YES

Claims NONE NO

Inventive Step (IS)

Claims NONE YES

Claims 1-34 NO

Industrial Applicability (IA)

Claims 1-34 YES

Claims NONE NO

### 2. CITATIONS AND EXPLANATIONS

Please See Continuation Sheet

**INTERNATIONAL PRELIMINARY EXAMINATION REPORT**International Publication No.  
PCT/US03/07067**Supplemental Box**

(To be used when the space in any of the preceding boxes is not sufficient)

**V. 2. Citations and Explanations:**

Claims 1-34 lack an inventive step under PCT Article 33(3) as being obvious over US 4,534,892 in view of WO 00/09641.

US 4,534,892 teach a foaming liquid detergent composition for applications such as shampoos, liquid cleanser etc., comprising a water-insoluble fine powder, an inorganic salt and a crosslinked amphoteric polymer (col. 2). For insoluble fine powder, US 4,534,892 teach silicon dioxide, aluminum oxide, calcium oxide etc., having a particle size of less than 150 microns, preferably 15-40 microns for a liquid cleanser and 0.1 to 5 microns for a detergent for body application (col. 6). US 4,534,892 do not teach the particles in hair volume enhancing amounts or a specific combination (percentages) of inorganic materials comprising bioactive glass (as claimed). US 4,534,892 teach addition of surfactants, viscosity enhancers, antioxidants, preservatives etc., in the composition.

WO 00/09641 teach a multifunctional detergent material useful in laundry and cleaning products compositions containing functional ingredients such as phosphorus oxide, sodium oxide and silicon dioxide, in the same amounts or percentage ranges as claimed (page 5). WO 00/09641 teaches the detergent material as filler, surfactants etc. or a builder (page 9) in laundry and cleaning products. WO 00/09641 also teaches incorporating additives such as chelating agents, enzymes (page 13), optical brighteners etc. WO 00/09641 does not teach the composition for hair in particular, however, mentions that the composition is used as cleansing product. Therefore, choosing the specific combination of silicon dioxide, phosphorus oxide and calcium oxide from the fine powder materials of US 4,534,892 would not involve an inventive step because WO 00/09641 teaches that such a multifunctional detergent material gives the cleansing composition a function such as filler or builder. Alternatively, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to use the composition of WO for hair treating applications such as a shampoo because US 4,534,892 teaches that the same inorganic materials are used in fine particulate forms for improving the foaming capacity of the hair cleansing composition. Further, US 4,534,892 also suggest that a pH of 6-8 is used for dispersing the fine particulate powder.

Claims 1-34 meet the criteria set out in PCT Article 33(2) because the prior art does not disclose using the composition containing particulate bioactive glass for enhancing hair volume.

Claims 1-34 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

**RESPONSE TO ARGUMENTS:** Applicants argue that instant claims 1-34 are inventive because the claimed method of treating hair for enhancing hair by the application of bioactive glass powder is not taught by US 4,534,892 or WO 00/09641. Applicants argue that in the claimed invention the bioactive glass composition releases ions such as calcium, phosphorus, which form a coating or film on the hair and thus enhance hair. Applicants argue that the prior art WO 00/09641 only teaches MFDM for their use as filler or builder in laundry and cleaning products, but not in hair enhancing. However, instant claims

**INTERNATIONAL PRELIMINARY EXAMINATION REPORT**

International Application No.  
PCT/US03/04887

**Supplemental Box**

(To be used when the space in any of the preceding boxes is not sufficient)

only recite "method of treating hair" and for "enhancing hair" but does claim a method of enhancing hair. Accordingly, the instant claims do not have any inventive step over the prior art of record.